

JUN 14 2013

Section 5 510(k) Summary (Revised 04/17/2013)

This revised 510k summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

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Date of Original Submission: November 30, 2012

Device Name and Classification

Product Name: LH80 PRO
Laser Helmet
Infrared lamp per 21 CFR 890.5500
Product Code: OAP
Regulation Number: 21 CFR 890.5500
Panel: General and Plastic Surgery
Class: II

Substantial Equivalence claimed to: Theradome, Inc. LH80 PRO Laser Helmet (K113097)
Midwest RF, LLC MEP-90 (K091496)

Device Description

The Theradome Laser Helmet LH80 PRO is a low level laser therapy (LLLT) device used to promote hair growth via photobiostimulation. The lasers are contained inside a lightweight, one-size fits all helmet. The LH80 PRO utilizes 80 laser diodes in the helmet to deliver laser stimulation to the entire scalp for hands-free operation during treatment. The device is one-button operated, and has an audible timer that automatically turns the lasers off after the 20 minute treatment completes.

Intended Use

The Theradome Laser Helmet LH80 PRO is intended to treat androgenic alopecia in adult females. The treatment schedule is 20 minutes twice a week on non-consecutive days. An audible timer automatically turns the lasers off after the 20 minute treatment completes. The laser helmet is not a safety helmet.

Technological Characteristics

The LH80 PRO delivers visible red low-level laser radiant energy to the scalp. The LH80 PRO utilizes 80 laser diodes to deliver laser stimulation to the entire scalp for hands-free operation during treatment.

Performance Characteristics

Testing to IEC 60601-1 and 60601-1-2 confirm the device's safety and electrical compatibility. Testing to IEC 60825-1 certifies the laser system to classification 3R, same as predicate devices.

Studies Related to Over-the-Counter Use

Two studies were conducted that were specifically intended to demonstrate that the device is appropriate for consumer use by lay persons.(see data and report attached)

Unbiased Participant Selection Process – (both studies)

These participants represent a wide range of education level attainment. Participants will not be trained, coached or assisted during the study. Potential study participants will be selected in a totally unbiased way. We will find participants in the downtown San Francisco commuter train station (Bay Area Rapid Transit) BART. Study administrators will be at this location and ask persons randomly who are entering or exiting the train station, if they will participate in a very brief survey. Those who say yes will then, be taken aside and their demographics will be recorded as outlined below. The study administrators will not question people about their hair in any way. All those who want to take the survey will be accepted as long as they meet the basic eligibility criteria listed below (page 2) for age, gender and understanding the English language. This technique will eliminate any potential for bias.

Self-Selection Study

The purpose of the study was to determine if a lay person could read the product labeling and then self-assess if the Laser Helmet LH80-PRO would be beneficial for them to use. This study was designed and a study protocol was developed. Raw data collection sheets were also designed, prepared and used during the study for raw data collection. Participants in the study were selected based on certain criteria. Details are described in section 22, page 77, and Attachments 22-1 through Attachment 22-10, of the 510(k) submission # K122950. Study data was collected from 31 Participants and then their hair condition was also examined by a physician who then decided if the person actually had Androgenic Alopecia or not. The results were that 30 participants did the self-assessment correctly, and one person did not select correctly. Then, the physician examination verified that 30 of the 31 participants correctly self- assessed their condition.

The conclusion was that 97% of the lay person consumers would be able to self-assess their need for the LH80-PRO based on their reading of the labeling on the packaging.

Labeling Comprehension Study

The purpose of this study was to determine if a lay person consumer could read and correctly comprehend the product labeling. This study was designed and a study protocol was developed. Raw data collection sheets were also designed, prepared and used during the study for raw data collection. Participants in the study were selected based on certain criteria. Details are described in section 22 of the 510(k) submission # K122950. Study data was collected from 31 Participants. Each participant was asked a series of questions by the study administrators staff. Some of the questions asked were:

1. Did the participant correctly identify their level of hair loss? Yes No
2. Did the participant correctly identify their skin tone type? Yes No
3. Based on the participants hair loss level and skin tone, were they then able to correctly identify if the laser helmet LH80-PRO was right for them? Yes No

Copies of the raw data collection forms are attached as (**Attachments A and C**). The results of the study were compiled and analyzed. The report containing the conclusions is attached here as (**Attachment J**). In summary, the conclusions were that an average lay person can read and comprehend correctly the package labeling and instructions.

Nonclinical Testing

Performance testing was conducted to confirm compliance to design specifications; all functions were verified to operate as designed. The tests performed and the acceptance criteria applied for each are listed in section 18.

Substantial Equivalence

Theradome, Inc. wishes to use the following devices as predicates:

Theradome, Inc. LH80 PRO Laser Helmet (**K113097**)

Midwest RF, LLC MEP-90 (**K091496**)

The LH80 PRO has the same intended use as the predicate devices: treat androgenic alopecia with red low level laser light classification 3R. The LH80 PRO shares the same indication for treating females as the MEP-90 and earlier LH80 PRO (Ludwig-Savin Hair Loss I-II and Fitzpatrick Skin Type I-IV).

The FDA Cleared MEP-90 device and cleared LH80 PRO device and the new LH80 PRO referred to in this submission all deliver treatment to the entire scalp for hands-free operation during treatment, and have the same treatment schedule.

The LH80 PRO has a 678nm center wavelength and the predicate devices' have 678nm center wavelength respectively. This does not change the intended use of the product nor does it affect the product's fundamental scientific technology. Therefore this change does not raise new questions about safety or effectiveness.

For these reasons, the Theradome Laser Helmet LH80 PRO satisfies FDA's substantial equivalence with respect to both intended use and technological characteristics.

The LH80 PRO has the same intended use and Indications for Use as the second Predicate device is the Midwest RF, LLC model **MEP-90**. The LH80 PRO shares the same indication for treating females as the LH80 PRO (Ludwig-Savin Hair Loss I-II and Fitzpatrick Skin Type I-IV).

The FDA Cleared MEP-90 device and the FDA cleared LH80 PRO device and the LH80 PRO referred to in this submission, all deliver treatment to the entire scalp for hands-free operation during treatment, and have the same treatment schedule.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 14, 2013

Theradome, Inc.
% Mr. Larry Petersen
4900 Hopyard Road, Suite 100
Pleasanton, California 94588

Re: K122950
Trade/Device Name: Laser Helmet LH80 PRO
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: April 22, 2013
Received: May 02, 2013

Dear Mr. Petersen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

~~You may, therefore, market the device, subject to the general controls provisions of the Act.~~ The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

Device Name: Theradome Laser Helmet LH80 PRO K122950

Indications for Use:

The Theradome Laser Helmet LH80 PRO is an over the counter (OTC) device indicated to treat androgenic alopecia, to Promote hair growth in females with female pattern hair loss (FPHL) on the Ludwig and Savin Hair Loss Scale I-II, Fitzpatrick Skin-Types I to IV:

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
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(Division Sign-Off) For MXM

Division of Surgical Devices

510(k) Number K122950